REMARKS

Reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

Status

As is correctly reflected in the Office Action Summary, Claims 1 and 6-38 are pending. Claims 18-30 have been withdrawn from consideration. Claims 1, 6-17, and 31-38 stand rejected. Acknowledgment has been made to a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f) and all certified copies of the priority documents have been received.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Applicants note with appreciation that the rejections under 35 U.S.C. § 112, Second Paragraph, have been withdrawn. *See Official Action, Page 2.*

Rejection Under 35 U.S.C. § 103(a) — Boussouira In View of Wheeler And/Or Berry

Claims 1, 6-17, and 31-38 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent No. 6,153,205 to Boussouira *et al.* ("Boussouira") in view of "*The biosynthetic pathway of vitamin C in higher plants*," by Glen L. Wheeler *et al.* ("Wheeler") and/or U.S. Patent Application Publication No. 2002/0012979 A1 to Berry *et al.* ("Berry"). *See Official Action, Pages 2-6.* This rejection is respectfully traversed.

Before reaching the merits of the pending rejection, Applicants wish to stress that when applying 35 U.S.C. § 103, four tenets of patent law must be adhered to: (1) the claimed invention must be considered as a whole, (2) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination, (3) the references must be viewed without the benefit of impermissible hindsight vision, and (4) a reasonable expectation of success is the standard with which obviousness is determined. *See M.P.E.P. § 2141*, citing *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 (Fed. Cir. 1986). To establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation to modify the reference or to combine reference teachings, (2) there must be a reasonable expectation of success, and (3) the prior art reference(s) must teach or suggest all of the claim limitations. *See M.P.E.P. § 2142; see also SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1356(Fed. Cir. 2000) (explaining that if a reference needs to be modified to achieve the claimed invention "there must be a showing of a suggestion or motivation to modify the teachings of that reference to the claimed invention in order to support the obviousness conclusion.").

Applicants respectfully maintain that a *prima facie* case of obviousness has not been made out.

Applicants' Claimed Invention

In deciding whether a *prima facie* case of obviousness has been made out, it is important to keep in mind what Applicants have claimed. In the instant application, Applicants claim not simply ascorbic acid, but *compositions for topical application*

comprising: (1) at least one ascorbic acid precursor that is *not* an ascorbic acid ester and that *is* L-galactono-1,4-lactone, L-gulono-1,4-lactone, D-glucorono-1,4-lactone, D-glucoronic acid, D-mannose, D-galacturonic acid, D-glucose, D-galactose, L-galactose, or mixtures thereof; and (2) at least one enzyme that converts said ascorbic acid precursor to ascorbic acid.

Boussouira

The foundation for the pending § 103(a) rejection is based upon Boussouira. Boussouira, like Applicants, explains that while ascorbic acid, Vitamin C, has many beneficial attributes (*see, e.g., Boussouira Column 1, Lines 19-24*), it is unstable and sensitive to external factors such as light and heat. *See Boussouira Column 1, Lines 36-38.* Unfortunately, "[t]his instability goes against the desired efficacy and, what is more, can be the source of unpleasant sensations for the user, for example when the instability of the active agent leads to changes in the color and/or odor of the composition containing it." *Boussouira Column 1, Lines 38-42.* Boussouira then explains that several solutions have been proposed for stabilizing active ingredients such as Vitamin C, but those solutions have presented other difficulties, such as a decrease in efficacy and prevention of rapid release of Vitamin A in sufficient quantity. *See Boussouira Column 1, Lines 49-59.* Boussouira concludes that there is "a need for a topical application product containing vitamins used in cosmetics and/or dermatology, in which these vitamins conserve all their properties and thus their efficacy over time." *Boussouira Column 1, Lines 60-63.*

According to Boussouira, EP 710,478 satisfies that need by using lipase with esters of Vitamin C. *See Boussouira Column 1, Lines 64-67.* Boussouira announces that he has discovered another way to satisfy that need by introducing C_6 to C_{22} alcohols into

compositions having lipase and Vitamin C esters. *See Boussouira Column 2, Lines 1-4.* Boussouira's solution to the foregoing Vitamin C problem is to ensure that his products have: (1) a lipase; (2) at least one precursor of a vitamin wherein the precursor is an ester; (3) at least one C_6 to C_{22} alcohol; and (4) a ratio of alcohol to precursor of 0.25 to 30/1. *See, e.g, Boussouira Claim 1.*

There Is No Motivation To Modify And Combine Boussouira With Wheeler or Berry Because Boussouira Teaches Away From Applicants' Invention

As explained above, to establish a *prima facie* case of obviousness, there must be some suggestion or motivation to modify the reference or to combine reference teachings. To arrive at Applicants' invention using Boussouira, one must modify **completely** Boussouira's requirement that the composition contain a Vitamin C *ester*. Applicants' compositions specifically ***exclude*** Vitamin C esters. There is nothing in Boussouira to suggest to or motivate one of skill in the art to disregard that which Boussouira has emphasized as critical to the success of his compositions. That is, there is nothing in Boussouira that suggests or motivates one of skill to exclude Vitamin C esters.

The Examiner has stated that "Boussouira clearly teaches compositions of ascorbic acid precursors in combination with enzymes will effectively produce the active vitamin." *See Official Action, Page 5.* This statement ignores the important fact that Boussouira's precursors must be esters, whereas Applicants' precursors must not be esters. Not only does Boussouira fail to suggest to or motivate one to modify its ester precursor attribute, it teaches away from doing so by emphasizing the beneficial combination of lipase, ester vitamin precursor, C_6 to C_{22} alcohol, and alcohol to precursor ratio.

Moreover, ascorbic acid may be produced according to several pathways. Boussouira relies upon the fact that acid ascorbic esters are naturally cleaved by esterases, whereas Applicants' invention relies upon a synthesis mechanism involving sugars. Nothing in Boussouira suggests to or motivates one to pursue a different pathway, especially in light of Boussouira's claim that only he and EP 710,478 (which share the lipase plus ester combination) overcome past difficulties with active ingredients such as Vitamin C.

Neither Wheeler Nor Berry Cure Boussouira's Deficiencies

Even if one of skill in the art were somehow prompted prior to Applicants' invention to disregard the ester precursor mandate of Boussouira, Applicants maintain he would not have looked to either Wheeler or Berry for guidance.

Boussouira is directed to topically-applicable compositions and methods for making such compositions containing a lipase, an ester vitamin precursor, a fatty alcohol, and a particular alcohol to precursor ratio. Wheeler is directed not to compositions, let alone topically-applicable vitamin precursor ester/lipase/fatty alcohol compositions, but to a proposed pathway for ascorbate biosynthesis in higher plants. *See Wheeler, Page 368, ¶ 2.* As a result of the experiments conducted and the conclusions drawn therefrom, Wheeler concludes only that "[w]e are now in a position to investigate the subcellular localization and control of ***ascorbate*** biosynthesis in ***plants*** and, ultimately, to manipulate its content with ***potential benefits*** for human nutrition and plant resistance to oxidative stress." *Wheeler, Page 368, ¶ 4* (emphasis added). Applicants disagree that one of skill in the art would look to *proposed ascorbate* pathways in *plants* which may eventually offer *potential benefits* for guidance in preparing compositions.

Applicants stress that the fact that Wheeler happens to disclose that "ascorbic acid precursors 1-galactose and 1-galactono-1,4-lactone are converted to ascorbic acid by 1-galactose dehydrogenase" is of no moment. *See Official Action, Page 4.* Mere identification of each claimed element in the prior art is NOT sufficient to negate patentability. *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). Instead, there "must be a teaching or suggestion within the prior art, or within the general knowledge of a person of ordinary skill in the filed of the invention, to look to particular sources of information, to select particular elements, and to combine them in the way they were combined by the inventor." *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 536 (Fed. Cir. 1998). Otherwise, sophisticated scientific fields would rarely, if ever, experience a patentable technical advance. *Rouffet*, 149 F.3d at 1357.

Similarly, Berry is as far afield from Boussouira as is Wheeler. Berry is directed not to compositions, let alone topically-applicable vitamin precursor ester/lipase/fatty alcohol compositions, but to methods for producing Vitamin C and esters thereof in microorganisms, genetically-modified microorganisms for producing Vitamin C and esters thereof, and to plants for producing Vitamin C and esters thereof. *See, e.g., Berry Claims 1-72.* Applicants disagree that one of skill in the art would look to information on *genetically-modified microorganisms* for guidance in preparing compositions.

Applicants respectfully reiterate that a *prima facie* case of obviousness has not been made out. Considering Applicants' invention as a whole and the cited publications as a whole, there is simply no motivation or suggestion to combine and modify Boussouira, Wheeler, and/or Berry as suggested by the Examiner. Moreover, due to the vast differences in subject matters covered by the cited publications, one of skill in the art — even if somehow prompted to select, modify, and combine the cited publications — would

not have expected to succeed in arriving at Applicants' invention, especially in light of Boussouira's mandate of using Vitamin A precursor esters. Finally, the cited publications do not disclose each and every element of Claims 1, 6-17, and 31-38.

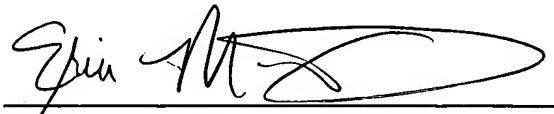
In light of the foregoing, Applicants respectfully request withdrawal of the remaining 35 U.S.C. § 103(a) rejection of Claims 1, 6-17, and 31-38 over Boussouira in view of Wheeler and/or Berry.

CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is respectfully requested and such action is earnestly solicited.

In the event that there are any questions relating to this response, or the application in general, it would be greatly appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that the prosecution of this application may be expedited.

Respectfully submitted,
BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: 

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